IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
EASTERN DIVISION
No. 4:22-CV-125

CODY RAY ASBY and CAROLINA ASBY,	)	
Plaintiffs,	)	
v.	)	**ORDER**
MEDTRONIC, INC., et al.,	)	
Defendants.	)	

On September 12, 2022, Cody Ray Asby and Carolina Asby ("the Asbys" or "plaintiffs") filed an action in Beaufort County Superior Court against Medtronic, Inc. ("Medtronic"), Medtronic USA, Inc., Medtronic Logistics LLC, Covidien LP ("Covidien"), Covidien Holding, Inc., and Covidien Sales LLC (collectively, "defendants") alleging claims of inadequate design, inadequate warnings or instructions, negligence, breach of implied warranty of fitness for a particular purpose, breach of express warranty, violations of North Carolina's Unfair and Deceptive Trade Practices Act ("UDTPA"), loss of consortium, and punitive damages [D.E. 1-1]. On October 14, 2022, defendants removed the action to this court [D.E. 1]. On October 21, 2022, defendants moved to dismiss the complaint [D.E. 12] and filed a memorandum in support [D.E. 13]. See Fed. R. Civ. P. 12(b)(6). On November 14, 2022, the Asbys responded in opposition [D.E. 18]. On November 28, 2022, defendants replied [D.E. 20]. As explained below, the court grant defendants' motion to dismiss and dismisses without prejudice the complaint.

I.

This case concerns the "EEA Circular Stapler with Tri-Staple Technology 28mm Medium/Thick" ("EEA Stapler"). Compl. [D.E. 1-1] ¶ 19 (cleaned up). Doctors use the EEA Stapler during surgery to form a seal between two internal bodily structures. See id. Defendants "designed, manufactured, and marketed" the EEA Stapler. See id. ¶¶ 20, 28.

On September 17, 2019, Cody Asby underwent a proctocolectomy procedure in which the surgeon used the EEA Stapler. See id. ¶ 30. During the procedure, the EEA Stapler became "stuck" in Cody Asby's tissue "thereby causing the J pouch to tear." Id. Asby alleges that this tear caused a permanent ostomy and led to several injuries and required multiple followup surgeries. See id. ¶¶ 32–48.

On August 17, 2018, over a year before Cody Asby's surgery, defendants initiated a recall of the EEA stapler due to identified issues regarding staple formation or inability to remove the device. See id. ¶ 21. The Asbys allege that the Food and Drug Administration ("FDA") determined that the cause of these issues was a process design. See id. The Asbys allege that defendants sought to conceal the "information and severity of the problems with the devices." Id. ¶ 23. Rather than submit reports through the public-access Manufacturer and User Facility Device Experience ("MAUDE") system, defendants allegedly used the non-public Alternative Reporting System ("ARS"). See id. The Asbys also allege that the defendants misled the FDA through the ARS system to hide the amount of fatalities and injuries and avoid "public disclosure and a recall." Id. ¶ 27.

II.

Defendants move to dismiss the complaint under Rule 12(b)(6). See Fed. R. Civ. P. 12(b)(6). A motion to dismiss under Rule 12(b)(6) tests the complaint's legal and factual sufficiency. See

Ashcroft v. Iqbal, 556 U.S. 662, 677–80 (2009); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 554–63 (2007); Coleman v. Md. Court of Appeals, 626 F.3d 187, 190 (4th Cir. 2010), aff'd, 566 U.S. 30 (2012); Giarratano v. Johnson, 521 F.3d 298, 302 (4th Cir. 2008). To withstand a Rule 12(b)(6) motion, a pleading "must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." Iqbal, 556 U.S. at 678 (quotation omitted); see Twombly, 550 U.S. at 570; Giarratano, 521 F.3d at 302. In considering the motion, the court must construe the facts and reasonable inferences "in the light most favorable to the [nonmoving party]." Massey v. Ojaniit, 759 F.3d 343, 352 (4th Cir. 2014) (quotation omitted); see Clatterbuck v. City of Charlottesville, 708 F.3d 549, 557 (4th Cir. 2013), abrogated on other grounds by Reed v. Town of Gilbert, 576 U.S. 155 (2015). A court need not accept as true a complaint's legal conclusions, "unwarranted inferences, unreasonable conclusions, or arguments." Giarratano, 521 F.3d at 302 (quotation omitted); see Iqbal, 556 U.S. at 678–79. Rather, a plaintiff's factual allegations must "nudge[ ] [his] claims," Twombly, 550 U.S. at 570, beyond the realm of "mere possibility" into "plausibility." Iqbal, 556 U.S. at 678–79.

When evaluating a motion to dismiss, a court considers the pleadings and any materials "attached or incorporated into the complaint." E.I. du Pont de Nemours & Co. v. Kolon Indus., Inc., 637 F.3d 435, 448 (4th Cir. 2011); see Fed. R. Civ. P. 10(c); Goines v. Valley Cmty. Servs. Bd., 822 F.3d 159, 166 (4th Cir. 2016); Thompson v. Greene, 427 F.3d 263, 268 (4th Cir. 2005). A court also may consider a document submitted by a moving party if it is "integral to the complaint and there is no dispute about the document's authenticity." Goines, 822 F.3d at 166. Additionally, a court may take judicial notice of public records without converting the motion to dismiss into a motion for summary judgment. See, e.g., Fed. R. Evid. 201; Tellabs, Inc. v. Makor Issues & Rts., Ltd., 551 U.S. 308, 322 (2007); Philips v. Pitt Cnty. Mem'l Hosp., 572 F.3d 176, 180 (4th Cir. 2009).

A.

In North Carolina, to maintain an inadequate design claim, a plaintiff must prove, inter alia, either:

> (1) At the time the product left the control of the manufacturer, the manufacturer unreasonably failed to adopt a safer, practical, feasible, and otherwise reasonable alternative design or formulation that could then have been reasonably adopted and that would have prevented or substantially reduced the risk of harm without substantially impairing the usefulness, practicality, or desirability of the product.
>
> (2) At the time the product left the control of the manufacturer, the design or formulation of the product was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design.

N.C. Gen. Stat. § 99B–6(a); see Earp v. Novartis Pharms. Corp., No. 5:11-CV-680, 2013 WL 4854488, at *6 (E.D.N.C. Sept. 11, 2013) (unpublished); DeWitt v. Eveready Battery Co., 144 N.C. App. 143, 154–55, 550 S.E.2d 511, 518–19 (2001), aff'd, 355 N.C. 672, 565 S.E.2d 140 (2002). Section 99B-6(b) provides a list of seven non-exclusive factors to consider when determining whether a manufacturer acted "unreasonably" under section 99B-6(b). See N.C. Gen. Stat. § 99B–6(b).[1]

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[1] N.C. Gen. Stat. § 99B–6(b) states:

> In determining whether the manufacturer acted unreasonably under subsection (a) of this section, the factors to be considered shall include, but are not limited to, the following:
>
> (1) The nature and magnitude of the risks of harm associated with the design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product.
>
> (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm.
>
> (3) The extent to which the design or formulation conformed to any applicable government standard that was in effect when the product left the control of its manufacturer.
>
> (4) The extent to which the labeling for a prescription or nonprescription drug approved by the United States Food and Drug Administration conformed to

The Asbys allege that the 2018 recall and FDA finding that there was a "process design" problem demonstrate inadequate design. See Compl. ¶ 21; [D.E. 18] 5. Defendants respond that the Asbys fail to plausibly allege that defendants acted unreasonably in designing the product, as required by the statute, and fail to plausibly allege any facts about the supposed inadequacy of defendants' design. See [D.E. 13] 5. Defendants also note that the Asbys fail to "describe any safer alternative design or identify a single aspect of product design that should have been changed." Id. at 6.

The Asbys fail to plausibly allege an inadequate design claim under N.C. Gen. Stat. § 99B–6(a). "Alleging negligent design requires alleging what was wrong with the design." Presnell v. Snap-On Securecorp., Inc., No. 1:20CV234, 2021 WL 1227062, at *3 (M.D.N.C. Mar. 31, 2021) (unpublished); Markel Am. Ins. Co. v. XDS, LLC, No. 7:20-cv-75, 2020 WL 4938435, at *4 n.5 (E.D.N.C. Aug. 24, 2020) (unpublished); Fields v. Jobar Int'l, Inc., No. 3:14-CV-50, 2014 WL 1513289, at *3 (E.D. Va. Apr. 16, 2014) (unpublished). The Asbys only offer the naked allegation that the EEA Staplers "frequently malfunctioned and were defective, compromising staple integrity and surgical procedures, with the potential to lead to patients' death or serious injuries when used by a surgeon, even as instructed by Defendants in the device user manual." Compl. ¶ 20. Not only

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any applicable government or private standard that was in effect when the product left the control of its manufacturer.

(5) The utility of the product, including the performance, safety, and other advantages associated with that design or formulation.

(6) The technical, economic, and practical feasibility of using an alternative design or formulation at the time of manufacture.

(7) The nature and magnitude of any foreseeable risks associated with the alternative design or formulation.

does the complaint fail to identify how the design is inadequate, but the complaint also fails to cite alternative feasible designs which were safer. See N.C. Gen. Stat. § 99B–6(a)(1).

To the extent that the Asbys rely on the FDA report and EEA Stapler recall to support their inadequate design claim, these factual allegations do not suffice. As defendants correctly note, the Asbys essentially have presented the court with two different, and inconsistent, theories about the EEA Stapler recall and the FDA report. In the complaint, the Asbys allege that the EEA Stapler was subject to a "Class 2" recall of the EEA Stapler, which is a recall of products that "may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." 21 C.F.R. § 7.3(m)(2); see Compl. ¶¶ 21, 47.[2] The complaint also alleges that, around the time of the recall, the FDA issued a report on malfunctions of surgical staplers which included data on staplers "designed, manufactured, and marketed by Defendants." Compl. ¶ 22. In their memorandum in opposition, however, the Asbys premise their arguments on different facts, namely that defendants' EEA Stapler allegedly was responsible for all the 110,000 reports of deaths and injuries included in the FDA report. See [D.E. 18] 13.

The FDA report and notice of recall contradict the Asbys' representation of the facts concerning the recall. See [D.E. 20-1]; [D.E. 20-2]. The FDA report on surgical staplers [D.E. 20-1], does not mention the defendants' EEA Stapler or anything about the EEA Stapler's design. Rather, the report broadly surveys the entire market and does not specifically mention any data about the EEA Stapler in particular. Moreover, the FDA notice of recall [D.E. 20-2] includes a statement from the FDA that there were "no reports of serious injury" prompting the recall. Therefore,

[2] In fact, the complaint is internally inconsistent on this point, in some places alleging that defendants initiated the recall and in others alleging that the FDA initiated the recall. Compare Compl. ¶ 21 with Compl. ¶ 47.

allegations regarding the 2018 recall and the FDA report do not plausibly support the Asbys' product liability claims.

As for N.C. Gen. Stat. § 99B–6(b), the Asbys have not plausibly alleged that the design of the EEA Stapler "was so unreasonable that a reasonable person, aware of the relevant facts, would not use or consume a product of this design." N.C. Gen. Stat. § 99B–6(b). Accordingly, the court dismisses without prejudice Asbys' inadequate design claim.

B.

The Asbys contend that defendants failed to properly warn Cody Asby's medical providers before surgery of the risks and potential dangers associated with the EEA Stapler. See Compl. ¶¶ 67–79; [D.E. 18] 7. The Asbys also argue that they do not have to plead how defendants' warnings were inadequate given that the complaint "is predicated on the knowledge and concealment Defendants perpetrated of the defects of its products, risks to patients, and the injuries its products were causing nationwide." [D.E. 18] 8. Defendants respond that plaintiffs have not plausibly alleged how defendants' warnings were inadequate and have failed to allege proximate cause. [D.E. 13] 8–9.

In order to maintain a failure to warn claim in North Carolina, a plaintiff must plausibly allege that "the defendant unreasonably failed to provide an adequate warning, such failure was the proximate cause of the plaintiff's damages, and the product posed a substantial risk of harm without an adequate warning either at the time of or after leaving the manufacturer's control." Carlson v. Bos. Sci. Corp., 856 F.3d 320, 324 (4th Cir. 2017) (cleaned up); see N.C. Gen. Stat. § 99B-5(a); Evans v. Evans, 153 N.C. App. 54, 57–58, 569 S.E.2d 303, 308 (2002); see also Teague v. Johnson & Johnson, Inc., 578 F. Supp. 3d 743, 750 (E.D.N.C. 2022). Moreover, the parties agree that the learned intermediary doctrine applies to a failure to warn claim. See [D.E. 13] 7–8; [D.E. 18] 7.

Under the learned intermediary doctrine, a manufacturer only needs to a provide warning to a health-care provider and need not warn the consumer directly. See Teague, 578 F. Supp. 3d at 749. Although North Carolina law explicitly applies the learned intermediary doctrine to prescription drugs, the doctrine also applies to medical devices. See, e.g., Salmon v. Parke, Davis, & Co., 520 F. 2d 1359, 1362 (4th Cir. 1975); Teague, 578 F. Supp. 3d at 749–50; Baraukas v. Danek Med., Inc., No. 6:97-CV-613, 2000 WL 223508, at *4 (M.D.N.C. Jan. 13, 2000) (unpublished); cf. N.C. Gen. Stat. § 99B-5(c).

The Asbys cite sections in the complaint allegedly containing specific allegations about how defendants failed to warn Cody Asby's health care providers. See [D.E. 18] 8; Compl. ¶¶ 22–23, 25, 70–76. These sections all concern defendants' use of the ARS reporting system rather than the MAUDE system and allege that defendants did not warn the health care providers about "foreseeable dangers inherent in the proper use of the EEA Stapler." Compl. ¶ 70; see [D.E. 18] 8; Compl. ¶¶ 22–23, 25, 71–76. These sections also discuss the FDA report on surgical staplers. See [D.E. 18] 8; Compl. ¶¶ 22–23, 25, 70–76.

The Asbys' allegations do not move their failure to warn claim from possible to plausible. First, the Asbys do not allege that Cody Asby's health care providers read or heard any of the defendants' warnings regarding the EEA Staplers, let alone relied on them. Without such allegations, the Asbys fail to plausibly allege the required proximate cause required to state a failure to warn claim. See, e.g., Carlson, 856 F.3d at 324; Frankum v. Bos. Sci. Corp., No. 1:15-CV-91, 2015 WL 3514327 at *2 (W.D.N.C. June 4, 2015) (unpublished). The Asbys respond that the complaint states that "[h]ad Plaintiff's surgeon been adequately warned," then the surgeon would not have recommended using the EEA Stapler. Compl. ¶ 77; see [D.E. 18] 8. This counterfactual,

however, does not allege that the surgeon actually read or relied on the warnings that defendants gave.

The Asbys also have failed to plausibly allege how any such warnings were inadequate. See, e.g., Proffitt v. Bristol-Myers Squibb Co., No. 1:17-04391, 2018 WL 3318893, at *4 (S.D.W. Va. July 5, 2018) (unpublished); Reed v. Pfizer, Inc., 839 F. Supp. 2d 571, 575–77 (E.D.N.Y. 2012). The Asbys' allegation that defendants were hiding from the public the risks of the EEA Stapler hinges on the allegation that the FDA report demonstrated over 100,000 injuries and deaths related to the product. See [D.E. 18] 13. The cited FDA report, however, discusses surgical staplers in general and does not link any of the reported malfunctions specifically to the EEA Stapler. See [D.E. 20-1]. If the Asbys are attempting to use the recall to support their failure to warn claim, the FDA specifically stated in the recall notice that it was not prompted by any reports of injuries or death. See [D.E. 20-2]. Thus, the allegation that defendants intentionally failed to warn consumers about the supposed injuries and deaths caused by the EEA Stapler is implausible. Accordingly, the court dismisses without prejudice the Asbys' failure to warn claim.

C.

The parties disagree whether under the North Carolina Products Liability Act (N.C. Gen. Stat. §§ 99B, et seq.) a plaintiff may allege a stand-alone common law negligence claim in a products liability action. Compare [D.E. 13] 11 with [D.E. 18] 9. The Asbys argue that defendants "failed to exercise ordinary care when they designed, manufactured, inspected, tested, assembled, promoted, distributed, marketed, and sold the EEA Stapler." Compl. ¶ 83. Defendants respond that these theories of negligence are inextricably tied to the underlying products liability claims. See id. ¶¶ 84–85.

In light of N.C. Gen. Stat. §§ 99B, et seq., "North Carolina law does not recognize an independent cause of action based on a failure to test or surveil one's product after marketing." Couick v. Wyeth, Inc., Civ. No. 09-210, 2012 WL 79670, at *7 (W.D.N.C. Jan. 11, 2012) (unpublished); see King v. Ethicon, Inc., No. CV 21-17983, 2022 WL 2341633, at *4–5 (D.N.J. June 29, 2022) (unpublished) (applying North Carolina law). The King court held that causes of action for failure to warn and defective design claims under N.C. Gen. Stat. § 99B-1(3) subsume independent negligence claims based on similar theories of liability. See King, 2022 WL 2341633, at *4 (holding that failure to instruct and train physicians, while relevant to the failure to warn claims, cannot stand as an independent theory of liability).

The Asbys' negligence claim regarding design, inspection, testing, promotion, distribution, and marketing are subsumed by the Asbys' failure to warn and ineffective design claims that the court already has dismissed. See Compl. ¶¶ 83–85. Likewise, the negligence claim involving manufacturing and assembly appears identical to the breach of warranty claims that the court dismisses in the following sections. See id. Accordingly, the court also dismisses without prejudice the Asbys' negligence claim.

Alternatively, if the negligence claim is not subsumed, the Asbys' negligence claim fails as a matter of law. Thus, the court dismisses without prejudice the Asbys' negligence claim.

D.

Under N.C. Gen. Stat. § 25–2–315, "an implied warranty of fitness for a particular purpose contemplates a use of a product that is peculiar or different from its ordinary use." NHM Constructors, LLC v. Heartland Concrete, LLC, No. 1:21-CV-100, 2022 WL 832578, at *7 (W.D.N.C. Feb. 28, 2022) (unpublished), report and recommendation adopted, No. 1:21-CV-100, 2022 WL 828958 (W.D.N.C. Mar. 18, 2022) (unpublished); see Ford Motor Credit Co. v. McBride,

257 N.C. App. 590, 595, 811 S.E.2d 640, 645–46 (2018); N.C. Gen. Stat. § 25–2–315. "Ordinary use of a product forecloses recovery under the implied warranty of fitness for a particular purpose." McDonald Bros., Inc. v. Tinder Wholesale, LLC, 395 F. Supp. 2d 255, 266 (M.D.N.C. 2005); see Presnell v. Snap-On Securecorp, Inc., 583 F. Supp. 3d 702, 714 (M.D.N.C. 2022).

The complaint alleges that the EEA Stapler is designed for use "in surgical procedures." Compl. ¶¶ 19–20. The complaint also alleges that a surgeon used the EEA Stapler on Cody Asby "during his proctocolectomy surgery." Id. at ¶ 30. Because the compliant alleges that a surgeon used the EEA Stapler in conformity with its ordinary use, the implied warranty of fitness for a particular purpose claim fails. See McDonald Bros., Inc., 395 F. Supp. 2d at 266; Presnell, 583 F. Supp. 3d at 714.

In opposition, the Asbys argue that Cody Asby's surgeon "had the particular purpose to use the stapler during surgeries to the rectal area of patients for proctocolectomy." [D.E. 18] 11. However, the complaint does not plausibly allege how a proctocolectomy surgery is so unique compared to other surgeries as to take this surgical procedure outside the EEA Stapler's ordinary use. Thus, the court dismisses without prejudice the Asbys' implied warranty of fitness for a particular purpose claim.

E.

Under N.C. Gen. Stat. § 25-2-313, a seller creates an express warranty through "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain[.]" N.C. Gen. Stat. § 25-2-313(1)(a); see Sasso v. Tesla, Inc., 584 F. Supp. 3d 60, 74 (E.D.N.C. 2022). To state a claim for breach of an express warranty, a plaintiff must plausibly allege: "(1) an express warranty as to a fact or promise relating to the goods, (2) which was relied upon by the plaintiff in making his decision to purchase, (3) and that this express

warranty was breached by the defendant." Harbor Point Homeowners' Ass'n, Inc. ex rel. Bd. of Dirs. v. DJF Enters., Inc., 206 N.C. App. 152, 162, 697 S.E.2d 439, 447 (2010) (quotation omitted); see City of High Point v. Suez Treatment Sols., Inc., 485 F. Supp. 3d 608, 627 (M.D.N.C. 2020); Ford Motor Credit Co., 257 N.C. App. at 596, 811 S.E.2d at 646. A plaintiff also must plausibly allege that "the breach proximately caused the loss sustained." City of High Point, 485 F. Supp. 3d at 627. Finally, a plaintiff must plausibly allege that the defect breaching the express warranty existed at the time of sale. See id. at 628; Riley v. Ken Wilson Ford, Inc., 109 N.C. App. 163, 170, 426 S.E.2d 717, 721 (1993); Pake v. Byrd, 55 N.C. App. 551, 554, 286 S.E.2d 588, 590 (1982).

The Asbys' express warranty claim fails because the complaint never identifies any express warranty made by any defendant. See Sasso, 584 F. Supp. 3d at 75 (noting that a plaintiff must identify "specific words, promises, affirmations, or statements . . . that would create an express warranty."). Indeed, the complaint fails to plausibly allege any language, contractual or otherwise, that would suggest the existence of an express warranty. Moreover, the court rejects the Asbys' argument that the marketing done by defendants constitutes an express warranty. See [D.E. 18] 12; cf. Sasso, 584 F. Supp. 3d at 75. Thus, the court dismisses without prejudice the Asbys' express warranty claim.

F.

The UDTPA declares unlawful "[u]nfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce . . . ." N.C. Gen. Stat. § 75-1.1(a). To state an unfair and deceptive trade practices claim, a plaintiff must plausibly allege: (1) an unfair or deceptive act or practice, (2) in or affecting commerce, and (3) which proximately caused injury to plaintiffs. Kelly v. Ga.-Pac. LLC, 671 F. Supp. 2d 785, 798 (E.D.N.C. 2009) (collecting cases); SciGrip, Inc. v. Osae, 373 N.C. 409, 426, 838 S.E.2d 334, 347 (2020); Walker v. Fleetwood Homes

of N.C., Inc., 362 N.C. 63, 71–72, 653 S.E.2d 393, 399 (2007). "A practice is unfair when it offends established public policy as well as when the practice is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers. A practice is deceptive if it has the capacity or tendency to deceive." Walker, 362 N.C. at 72, 653 S.E.2d at 399 (cleaned up). "[I]t is not necessary for the plaintiff to show fraud, bad faith, deliberate or knowing acts of deception, or actual deception, but plaintiff must show that the acts complained of possessed the tendency or capacity to mislead, or created the likelihood of deception." Gress v. Rowboat Co., 190 N.C. App. 773, 776, 661 S.E.2d 278, 281 (2008) (cleaned up); see Overstreet v. Brookland, Inc., 52 N.C. App. 444, 452–53, 279 S.E.2d 1, 7 (1981). However, a "mere breach of contract, even if intentional, is not an unfair or deceptive act." Waddell v. U.S. Bank Nat'l Ass'n, 395 F. Supp. 3d 676, 684 (E.D.N.C. 2019) (collecting cases); see Respess v. Crop Prod. Servs., Inc., No. 4:15-CV-00176, 2016 WL 3821163, at *5 (E.D.N.C. July 13, 2016) (unpublished); Mitchell v. Linville, 148 N.C. App. 71, 75, 557 S.E.2d 620, 623–24 (2001).

To state a claim based on alleged misrepresentations, a plaintiff must plausibly allege "reliance on the misrepresentation in order to show the necessary proximate cause." Bumpers v. Cmty. Bank of N. Va., 367 N.C. 81, 88–89, 747 S.E.2d 220, 226 (2013); see Johnson, 2022 WL 2447091, at *15; Sasso, 584 F. Supp. 3d at 79. "Reliance, in turn, demands evidence showing that the plaintiff suffered actual injury as a proximate result of defendant's deceptive statement or misrepresentation." Bumpers, 367 N.C. at 89, 747 S.E.2d at 227 (cleaned up); Rahamankhan Tobacco Enters. Pvt. Ltd. v. Evans MacTavish Agricraft, Inc., 989 F. Supp. 2d 471, 478 (E.D.N.C. 2013).

The heightened pleading standard under Federal Rule 9(b) "applies to unfair and deceptive trade practices claims based on alleged misrepresentations." Sasso, 584 F. Supp. 3d at 80; see, e.g.,

Cross v. Ciox Health, LLC, 438 F. Supp. 3d 572, 584–86 (E.D.N.C. 2020); Topshelf Mgmt., Inc. v. Campbell-Ewald Co., 117 F. Supp. 3d 722, 728–32 (M.D.N.C. 2015). Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "[T]he circumstances required to be pled with particularity under Rule 9(b) are the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 784 (4th Cir. 1999) (quotations omitted); see Edmonson v. Eagle Nat'l Bank, 922 F.3d 535, 553 (4th Cir. 2019).

The Asbys premise their UDTPA claim on allegations that defendants were "representing to Plaintiff's healthcare providers that the EEA Stapler was safe to use for the proctocolectomy surgery when it was actually defective." [D.E. 18] 13; Compl. ¶¶ 25, 108–10. The complaint, however, fails to plead with sufficient particularity under Federal Rule 9(b) who made these misrepresentations, when the defendants allegedly made the representations, and the alleged content of these misrepresentations. To the extent the Asbys cite the alleged breach of warranty as the deceptive act, a breach of warranty claim does not suffice to state a UDTPA claim. See, e.g., Sasso, 584 F. Supp. 3d at 80; Buffa v. Cygnature Constr. & Dev., Inc., 251 N.C. App. 526, 796 S.E.2d 64, at *7 (2016) (unpublished table decision).

The Asbys also suggest that defendants were attempting to mislead or defraud the Asbys and other consumers by using the ARS system rather than the MAUDE system. See [D.E. 18] 13 ("Defendants used an [ARS] rather than the publicly accessible database ran by the FDA in an attempt to diminish reports, so the resulting injuries of the defective EEA Stapler seemed less threatening."). This claim, however, merely repackages the Asbys' dismissed failure to warn claim with the added allegation that defendants intentionally used the ARS system in order to mislead or

defraud the public. Moreover, to the extent the Asbys believe that defendants attempted to mislead the FDA about the EEA Stapler through defendants' ARS filings, such a fraud on the FDA claim is preempted. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350–53 (2001). Accordingly, the court dismisses without prejudice the Asbys' UDTPA claim.[3]

III.

In sum, the court GRANTS defendants' motion to dismiss [D.E. 12] and DISMISSES WITHOUT PREJUDICE plaintiffs' complaint. Plaintiffs may file an amended complaint not later than June 5, 2023.

SO ORDERED. This 18 day of May, 2023.

JAMES C. DEVER III
United States District Judge

[3] The complaint also contains a request for loss of consortium damages and punitive damages. In light of the failure of plaintiff's substantive claims, plaintiffs' derivative requests for damages also fail. See Trivette v. Yount, 366 N.C. 303, 313, 735 S.E.2d 306, 313 (2012); Bryant v. Wake Forest Univ. Baptist Med. Ctr., 281 N.C. App. 630, 645, 870 S.E.2d 269, 279 (2022); Iadanza v. Harper, 169 N.C. App. 776, 783, 611 S.E.2d 217, 223 (2005). Thus, the court dismisses these derivative requests.